UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,555	12/08/2003	Katerina Heran Darwin	19603/4292 (CRF D-3099-03	3247

7590 07/28/2005

Michael L. Goldman, Esq.
NIXON PEABODY LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603

EXAMINER	
ODELL, LINDSAY T	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,555	DARWIN ET AL.	
	Examiner	Art Unit	
	Lindsay Odell	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) *7-11,21-62,69-73 and 88-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12-20,63-68 and 74-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *21 October 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (mailed on April 7, 2004), Applicants filed a response received on June 6, 2005. Claims 1-102 are pending in this instant Office action.

Election

2. Applicant's election with traverse of Group II, Claims 1-6, 12-20, 63-68 and 74-87, drawn to methods of inhibiting a proteasomal activity in a pathogen where said activity is a proteasomal protease activity, and election of the species PrcB, which reads on claims 1-4, 6, 12-20, 63-67 and 74-87, in the reply filed on June 6, 2005 is acknowledged. The traversal is on the ground(s) that the Groups of inventions are related one another and require common areas of search. This is not found persuasive because the Groups of claims are distinct for the reasons previously cited, and the searches are not *co-extensive* because the groups are classified differently and/or the searches in textual databases are different; thus, the Groups of claims would be burdensome to be searched together. The traversal for the election of species requirement is on the grounds that the species relate to a single inventive concept. This is not found persuasive because the requirement for an election of species is based on patentable distinctness, not unity of invention (see MPEP § 1.146). The species are patentably distinct for the following reason: they have different structures (i.e. different amino acid sequences) and different functions (i.e. enzyme or protein activity). In addition, it would be burdensome to

search all the species together because the searches in textual and amino acid databases are different (i.e. not co-extensive).

The requirement is still deemed proper, and is, therefore, made FINAL.

With regard to the matter of the dependency of claim 65, the Examiner agrees with the Applicant that claim 65 properly depends from claim 64. Thus, claim 64 has been included in the group of claims that link inventions I and II.

Claims 1-102 are pending in the instant Office action. Claims 7-11, 21-62, 69-73 and 88-102 are withdrawn as non-elected inventions. The Examiner has extended examination to include the species PrcA in claims 5 and 68. Claims 1-6, 12-20, 63-68 and 74-87, to the extent that they read on the elected invention, are examined herein.

Priority

3. The instant application is granted the benefit of priority for the U.S. provisional Application No. 60/431676 filed on December 6, 2002 and the U.S. provisional Application No. 60/471774 filed on May 19, 2003 as requested in the declaration and the first lines of the specification.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed October 21, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following reference were not considered for the reasons described below:

a) The listing of references for citation number 9 is improper. Only one reference may be cited for each designated letter group, however, two references are cited for entry number 9. The Examiner suggests listing the supplemental *erratum* document as a separate entry, and added the author's name and the title.

All other documents in said Information Disclosure Statement were considered as noted by the examiner's initials in the attached copy.

Compliance with Sequence Rules

5. The sequence listing, filed in computer readable form (CRF) and paper copy on December 8, 2003 has been received and entered.

Objections to the Specification

6. The specification is objected to because the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: ---Methods of treating *Mycobacterial* infection in a subject by inhibiting *Mycobacterial* proteasomal protease activity---.

7. The abstract of the disclosure is objected for not completely describing the disclosed subject matter (MPEP § 608.01(b)). It is noted that in many databases and in foreign countries the Abstract is crucial in defining the disclosed subject matter; thus, its completeness is essential. The Examiner suggests the inclusion of the species of the pathogen that is inhibited by the methods of treating pathogen infection, *Mycobacterium tuberculosis*; recitation of the activity

names and the proteins whose proteasomal, protease or enzymes activities are inhibited by the methods of treatment (i.e. AAA ATPase encoded by the groEL1 and Rv2115c genes, PrcA protease, PrcB protease, excision-repair enzyme UvrB); and recitation of the inhibitors used in the methods of treating pathogen infection (i.e. epoxomicin and N-[4-morpholine]carbonyl-β-[l-naphtyl]-L-alanine-L-leucine boronic acid), for completeness.

8. The specification is objected for the following informality: on page 13 in paragraph 0039, the specification disclosed the compound "N-[4-morpholine]carbonyl-beta-1[1-naphthyl]-L-alanine-L-leucine boronic acid (MLN-273)", which is confusing because the instant compound is not known as MLN-273 in the art (see Kisselev *et al.,* IDS). The compound is referred to as MLNB, MG 273, and PS-273; however, there is no compound found in the art called "MLN-273". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6, 12-20, 63-68 and 74-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "conditions effective to make the pathogen susceptible . . " to antibacterial host defenses (claims 1-6, 15-20, 63-68, 74-81 and 85-87) or oxidative or nitrosative stress (claims 12-14 and 82-84) is unclear as to the metes and bounds it imparts on the claimed subject matter. The conditions effective to make the instant pathogens

susceptible are not defined in the specification, nor are they clearly and singularly defined in the art. It is unclear what constitutes the instant conditions. Clarification is required.

10. Claims 1, 12-20, 63 and 74-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "proteasomal activity" is unclear as to the metes and bounds of the claimed subject matter. A definition for the term is not found in the specification, nor is it defined in the art with a single meaning. Does Applicant mean to claim any activity related to regulating the proteasome (for example, that of AAA ATPase) or only activities carried out by the proteasome, itself. Furthermore, the eukaryotic proteasome is disclosed in the art as having different types of enzymatic activities (i.e. chymotrypsin-like activity, trypsin-like activity), however, the activity of prokaryotic proteasomes is less-well defined. Exactly what type of enzymatic activity is a "proteasomal activity"? Clarification is required.

11. Claims 2-3 and 64-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "proteasomal protease activity" in claims 2-3 and "protease activity" in claims 64-65 in the phrases "wherein the proteasomal activity is . . . a *proteosomal protease activity*" (emphasis added) and "wherein the proteasomal activity is . . . a *protease activity*" (emphasis added) is confusing. It is unclear from the specification and the art what other types of activities the proteasome has besides protease activity. Are the terms meant to exclude proteases that affect proteasomal activity, but are not part of the proteasome?

Furthermore, the eukaryotic proteasome is disclosed in the art as having different types of enzymatic activities (i.e. chymotrypsin-like activity, trypsin-like activity), however, the activity of prokaryotic proteasomes is less-well defined. Exactly what type of enzymatic activity is a "proteasomal activity protease activity" or a "protease activity"? Clarification is required.

12. Claims 3 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "proteasome core" is unclear as to the metes and bounds it imparts on the claimed subject matter. It is unclear what constitutes the proteasome core of a proteasome. A definition for the term is not found in the specification, nor is it defined in the art with a single meaning. While the eukaryotic proteasome is described as having a 20S (700kDa) core on page 30 of the specification, however the exact polypeptides that define the core are not disclosed. Furthermore, it is unclear exactly what defines the proteasomal core in prokaryotic proteasomes. Clarification is required.

13. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4-6 recite the limitation "wherein the *protease* . . ." emphasis added. There is insufficient antecedent basis for this limitation in the claim. Claim 3, upon which claims 4-6 depend recites "wherein proteasomal activity is *proteasomal protease* activity" (emphasis added). It is unclear if Applicant means to claim a protease that is a "proteasomal protease activity or merely a "protease activity". The latter interpretation could include proteases

that affect proteasomal activity, but that are not part of the proteasome, whereas the former interpretation could include only proteases that are part of the proteasome. The Examiner suggests substituting the term "protease" in claims 4-6 with the term "proteasomal protease". Clarification is required.

14. Claims 4-6 and 64-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear exactly which protease must be inhibited. A gene named *prcBA* is known for *Mycobacterium tuberculosis*, but claims 4 and 64 are drawn to methods of inhibiting the protease activity of the protease encoded by the *prcBA* genes in any pathogen. The nature of the proteases encoded by the *prcBA* genes, PrcA and PrcB, is wholly unclear. Are proteases encompassed by the breadth of the claims only those that are exactly named PrcA and PrcB or encoded by the gene *prcBA?* Or, are proteases that have the same function as the instant proteases, but a different name, encompassed by the breadth of the claims? Clarification on all of the above points is required.

15. Claims 12-14 and 82-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "oxidative/nitrosative stress" in claims 12 and 82, the term "reactive nitrogen intermediate-induced stress" in claims 13 and 83, and the term "reactive oxygen intermediate-induced stress" in claims 14 and 84 are unclear as to the metes and bounds they impart on the claimed subject matter. Definitions for the instant terms **are** not

disclosed in the specification. In addition, the terms are not clearly defined in the art with a single meaning. It is unclear how to assess when a pathogen is specifically susceptible to any of the instant types of stress. Clarification is required.

16. Claim 77 ~~is~~ and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear exactly which enzymes must be inhibited. Clear definitions for the terms "DNA repair enzyme" and "flavin-like co-factor synthesis enzyme" are not found in the specification, nor are they defined clearly in the art with a single meaning. The exact nature of a "DNA repair enzyme" and "flavin-like co-factor synthesis enzyme" is not clear. Is any enzyme that acts on DNA considered a DNA repair enzyme (i.e. restriction enzymes), or only enzymes that repair particular types of damage to DNA? How similar to does a "flavin co-factor" does a molecule have to be to be considered a "flavin-like co-factor"? Furthermore, what are the enzymes involved in "flavin-like co-factor synthesis? What structure does an enzyme have to have to be considered a "DNA repair enzyme" or a "flavin-like co-factor synthesis enzyme"? Clarification on all of the above points is required.

17. Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear exactly which enzymes must be inhibited. A clear definition for the term "nucleotidase excision-repair enzyme" is not found in the specification, nor is defined clearly in the art with a single meaning. The exact nature of a "nucleotidase excision-repair

enzyme " is not clear. Does a nucleotidase excision-repair enzyme have to both excise and join DNA or can it do only one or the other? Furthermore, it is not clear exactly what constitutes DNA repair (see above). What does "nucleotidase excision-repair enzyme" look like (i.e. what is it's structure?). Clarification on all of the above points is required.

18. Claims 79-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear exactly which enzyme must be inhibited. A clear definition for the term "*uvr* gene family" in claim 79 and "UvrB" enzyme in claim 80 is not found in the specification, nor is defined clearly in the art with a single meaning. It is unclear exactly which genes belong to the *uvr* gene family. Does a gene have to be named exactly *uvr* to be a member of the family, or must it merely be an excision-repair enzyme with a similar structure to a *uvr* gene. What is the structure of products of *uvr* gene family, such as UvrB? A product of a *uvr* gene, UvrB, is known for *Mycobacterium tuberculosis*, but the claims are drawn to methods of inhibiting enzymes encoded by the *uvr* gene family or UvrB enzymes in any pathogen. The nature of the enzymes encoded by the *uvr* gene family, and UvrB are wholly unclear. Clarification on all of the above points is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-6, 12-20, 63-68 and 74-87 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to methods of inhibiting proteasomal activity in a pathogen under certain conditions in order to treat a pathogen infection (claims 1 and 12-20), wherein the proteasomal activity is a proteasomal protease activity (claims 2-6), and to methods of inhibiting proteasomal activity in a pathogen and inhibiting enzyme activity in a pathogen (claims 63 and 74-87), wherein the proteasomal activity is a protease activity (claims 64-68). The instant claims lack adequate written description for proteasomal and/or enzyme inhibitors used to inhibit proteasomal and enzyme activity.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical

characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (see *Enzo Biochemical*, 63 USPQ2D 1609, CAFC 2002).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from Enzo Biochemical (see above).

On pages 15-16 of the instant specification, two inhibitors of proteasomal activity, epoxomicin and MLN-273, are described. These inhibitors are not disclosed as acting specifically on proteasomal protease activity, such as that of PrcA or PrcB. No inhibitors are disclosed that act on DNA-repair enzyme activity. While protease and enzyme inhibitors are known in the art, a representative number of inhibitors that specifically act on proteasomal protease activity, such as *prcBA* gene product activity, and enzyme inhibitors that specifically inhibit DNA repair enzyme activity, such as UvrB, are not known. In addition, the common characteristics that define the structure of the genus of inhibitors of proteasomal protease activity and DNA-repair activity, are also not adequately described. In view of the prior art, one of skill in the art would be unable to predict the structure of members of this genus by virtue of the instant disclosure. Therefore, claims drawn to the instant genus of polypeptides are not adequately described.

20. Claims 1-6, 12-20, 63-68 and 74-87 are rejected under 35 U.S.C. 112, first paragraph, enablement. The claim(s) contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to methods of inhibiting proteasomal activity in a pathogen under certain conditions in order to treat a pathogen infection (claims 1 and 12-20), wherein the proteasomal activity is a proteasomal protease activity (claims 2-3), optionally a PvrA or PvrB activity (claims 4-6), and to methods of inhibiting proteasomal activity in a pathogen and inhibiting enzyme activity in a pathogen (claims 63 and 74-76 and 81-87), wherein the enzyme activity is a DNA repair enzyme activity, such as a UvrB activity (claims 77-80), wherein the proteasomal activity is a protease activity (claims 64-65), optionally a PvrA or PvrB activity (claims 66-68). To make the crystals and molecules that form crystals encompassed by the scope of the instant claims would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by

weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The specification contains no working examples of methods of inhibiting proteasomal activity in a pathogen to treat a pathogen infection. While the art provides guidance on the use of eukaryotic proteasome inhibitors, it provides little guidance on the use of inhibitors of pathogen proteasomes, which are largely prokaryotic. The nature of the invention is such that prokaryotic proteasomes differ in both structure and function from eukaryotic proteasome (Knipfer *et al.*, see IDS); thus, the effect of using inhibitors of eukaryotic proteasomes on prokaryotic proteasomes is unpredictable. The art contains no guidance on the use of specific inhibitors of the PrcA and PrcB proteasome subunits or the UvrB enzyme. While the instant specification describes methods for finding proteasomal protease inhibitors (see page 28), these methods do not enable one of skill in the art to find *and make* all, or a relevant portion of, the molecules within the scope of the claims. The ability to find an inhibitor of a proteasomal protease is not equivalent to the ability to make an inhibitor as required by the statute (i.e., "make and use"). Neither the specification nor the art provide guidance on the common structural characteristics that define the genera of inhibitors included in the scope of the claims. Without knowing the detailed structure of the members of the instant genera, the amount of

experimentation required to make such members if very high because the predictability of making them is low. The nature of the invention is such that the proteasomal and enzyme inhibitors can be any kind of molecule (i.e. protein, peptide, small molecule) that inhibits a proteasomal protease, PrcB, PrcA or an enzyme, such as UvrB; and with no guidance as to the common structure of such molecules, the predictability of functionality becomes extremely low. The breadth of the claims and the unpredictability of the art render the instant claims not enabled without undue experimentation.

Other Art for Comment/Examiner's Suggestions

21. The following is cited to complete the record:

a) Schubert *et al.* (see PTO-892) teach that inhibition of the proteasome with epoxomicin interferes Gag polyprotein processing and maturation of HIV-1 and HIV2 in infected cells; however, they do not teach inhibition of proteasomal activity in a pathogen, only inhibition of proteasomal activity in the host cell that is infected.

Conclusion

22. Claims 1-6, 12-20, 63-68 and 74-87 are rejected for the reasons identified in the numbered sections of the Office action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER

Lindsay Odell, Ph.D.
July 21, 2005